REMARKS

Status Summary

Claims 1, 3, 4, 6, 9-22, 24-29, 31-33 and 36-42 are pending in the present application. Claims 1, 3, 4, 6, 9-22, 24-29, 31-33 and 36-42 presently stand rejected. Claims 2, 5, 7, 8, 23, 30, and 34-35 were previously canceled. With this amendment, claims 1, 22, 38 and 42 have been amended. New claim 43 has been added. Reconsideration of the application is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 3, 4, 6, 9-10, 13-22, 24-28, 31-33, 36, 37, 40 and 41 stand rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,069,204 to Smith, et al. (hereinafter "Smith"). This rejection is respectfully traversed.

Independent claim 1 recites a drug delivery device for delivering to a patient a drug composition from a container which contains the drug composition. The container is adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto which is a movement of a first part of the container relative to a second part of the container. Claim 1 recites a dispensing unit adapted to receive the container. The dispensing unit has an actuating mechanism hand-operable to apply the actuating condition to the container, and an outlet through which the drug composition is dispensable from the device to deliver the drug composition as the patient inhales through the outlet. The actuating mechanism is configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container. Claim 1 recites a casing unit for the

dispensing unit. The casing unit is configured to be movable between a closed state in which the casing unit covers the outlet, and an open state in which the casing unit uncovers the outlet.

Claim 1 also recites that the dispensing and casing units have securing features for fixedly securing the units together. Additionally, claim 1 recites that the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state. Claim 1 recites that the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit. Claim 1 further recites that the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit.

Independent claim 22 recites a method of manufacturing a hand-operated drug delivery device for delivery of a drug formulated in a drug container which is adapted to be placed in a dispensing mode on application of an actuating condition thereto which is a movement of a first part of the container relative to a second part of the container. The method of claim 22 recites providing a dispensing unit for receiving the container with the dispensing unit having an actuating mechanism hand-operable to apply the actuating condition to the container and an outlet through which the drug formulation is dispensed on application of the actuating condition to the container to deliver the drug composition as the patient inhales through the outlet. The actuating mechanism is configured to hold the second part of the container stationary and to allow the first part

to move relative thereto for dispensing the drug composition from the container. The method of claim 22 also recites separately providing a casing unit adapted to fixedly hold the dispensing unit such that the drug is dispensable from the container by the dispensing unit when held by the casing unit. The casing unit is configured to be movable between a closed state in which the casing unit covers the outlet, and an open state in which the casing unit uncovers the outlet.

Additionally, claim 22 recites that the dispensing and casing units have securing features for fixedly securing the units together. Claim 22 recites that the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state. Claim 22 also recites that the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit. Claim 22 further recites that the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit.

Applicants respectfully submit that Smith does not anticipate independent claims 1 and 22 or the claims that depend therefrom as Smith does not disclose all the features of independent claims 1 and 22. For example, Smith does not disclose a drug delivery device with a dispensing unit that is configured to be hand-operated both when fixedly secured to the casing unit and when the dispensing unit is independent from the casing unit to deliver a drug composition as the patient inhales through an outlet of the device.

Smith discloses a breath-actuated inhaler as shown in Figures 1-3. The breath-actuated inhaler comprises a housing **2**, which presents a mouthpiece **4**, inside of which is movably disposed an aerosol canister **6**. The canister **6** comprises a valve (not shown) which in turn comprises a valve stem **8** located in a nozzle block **10** defined by the housing **2**. (See Smith, column 3, line 65-column 4, line 6.)

Located inside the housing **2** is a breath actuation mechanism which in normal use prevents the inhaler from being used until a patient inhales at the mouthpiece **4**. In Figure 1, the breath actuation mechanism is shown in a "blocking position" which prevents the aerosol canister **6** from being depressed toward the nozzle block **10** to open the valve, which would otherwise take place upon application of a force **A** being applied to the top of the canister **6**. (See Smith, column 4, lines 7-21.)

In more detail, the breath actuation mechanism of Smith comprises a pivotable vane **14**. The vane **14** resides in a "blocking position" where it sits in front of the discharge opening **12** of the nozzle block **10** when the vane is in a resting position as shown in Figure 1. When a patient inhales at the mouthpiece **4**, the vane **14** pivots away from the discharge opening **12** to lie against the roof of the mouthpiece **4** as shown in Figure 2. In this way, the vane **14** does not block discharge of content of the canister **6** through the mouthpiece **4** upon opening of the valve. (See Smith, column 4, lines 7-50.)

Notably, when the vane **14** is at rest in its blocking position, depression of the aerosol canister **6** to the extent needed to open the valve is prevented by a rocker element **15** of the breath actuation mechanism being fixed in position through

mechanical interaction of a catch **16**, pivotably mounted on the rocker element **15**, with the vane **14**. Thus, when the inhaler is in its breath-actuated mode it is not possible to dispense from the aerosol vial before inhalation through the mouthpiece **4**. (See Smith, column 4, lines 14-21.)

However, as shown in Figure 2, when a patient inhales at the mouthpiece **4** to cause the vane **14** to pivot against the roof of the mouthpiece **4**, the mechanical interaction between the catch **16** and the vane **14** is "broken" whereby the rocker element **15** can freely move to an unblocking position when the canister **6** is moved towards the nozzle block **10** in response to application of a downward force **A** thereto (See Smith, column 4, lines 22-34.)

With reference to Figures 4 and 5, the breath-actuated inhaler is detachably mountable inside an outer protective casing **34**. As shown in Figure 4, for instance, the protective casing **34** is provided with a cocking spring **48** which extends between an inside surface of the casing **34** and the top of the canister **6**. The protective casing **34** comprises a movable cover **38** for the mouthpiece **4**. As shown in Figure 5, when the movable cover **38** is moved from a mouthpiece covering position to a mouthpiece opening position, a cam **42** on the movable cover **38** moves the breath-actuated inhaler upwardly in the protective casing **34** and loads the cocking spring **48**. (See Smith, column 5, lines 5-44.)

The cocking spring **48** cannot push the canister **6** downwardly towards the nozzle block **10** as the breath actuation mechanism is in its blocking position. However, as described above, when a patient inhales at the mouthpiece **4**, the breath actuation

mechanism moves to its unblocking position thereby releasing the loading force in the cocking spring **48** to push the canister **6** downwards to release content therefrom.

The inability of the loaded cocking spring **48** to depress the canister **6** until a patient inhales at the mouthpiece **4** guarantees coordination of release of content from the canister **6** with patient inhalation.

Smith states as one of its advantages that the breath-actuated inhaler has the ability to work in the breath actuated mode both inside and outside of the protective casing **34**. (See Smith, column 2, lines 30-33.) When the inhaler is out of the protective casing **34**, a patient can manually apply the force **A** to the base of the canister **6** and this force will only cause actuation of the inhaler if a patient concurrently inhales at the mouthpiece **4**.

In addition, when the breath-actuated inhaler is outside the protective casing **34** it can also be put into a "press-and-breathe" mode where it is used without the breath actuation mechanism. As will be seen in Figure 3, the housing **2** of the inhaler carries a switch **22** which can be moved so as to deflect the catch **16** away from its connection with the vane **14** and thereby move the breath actuation mechanism to its unblocking position. Once the switch **22** has been so moved, the breath actuation mechanism provides no hindrance to downward movement of the canister **6** in response to manual application of a downward force **A** thereto. A difficulty will arise, however, if the patient does not inhale in coordination with this downward movement of the canister **6**, otherwise the vane **14** will still be in its normal rest position covering the discharge opening **12** of the nozzle block **10**. (See Smith, column 4, lines 35-53.)

Smith discloses and teaches that when the breath-actuated inhaler is located in the outer protective casing **34**, the inhaler is automatically converted to its breath-actuated mode, even if it is in the press-and-breathe mode, upon closing the movable cover **38** after loading the inhaler into the casing **34**. As can be understood from Figure 4, a flange **25** on the cover **38** acts on the switch **22** to ensure it is in the breath-actuated position. (See Smith, column 5, lines 40-44.)

Therefore, as can be taken from the detailed description above, Smith is concerned with a breath-actuated inhaler which can be used in its breath actuated mode both inside and outside of a protective casing. Moreover, when the breath-actuated inhaler is outside of its protective casing, the breath actuation mechanism can be disengaged so that it can be actuated in "press-and-breathe" mode. However, when the inhaler is in the protective casing, it can only operate in a breath-actuated mode that requires the patient to breathe in to create the actuating condition of movement of a first part of the vial relative to a second part.

As described above, claims 1 and 22 of the present application recite that the dispensing unit has an actuating mechanism which is hand-operable to apply an actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state. The actuating condition is movement of a first part of the container relative to a second part, and the actuating mechanism is configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing a drug composition from the container.

Smith does not disclose an actuating mechanism which is hand-operable to apply the actuating condition to the aerosol canister ("container") when the breath-actuated inhaler is fixed in the protective casing ("casing unit") with the casing in the open state. As stated above, when the breath-actuated inhaler of Smith is mounted in the protective casing, the actuating condition (downward force) is applied to the container by the cocking spring as a direct result of inhalation at the mouthpiece releasing the breath actuation mechanism. Breath operation causes the actuating condition, not hand operation as required by claims 1 and 22 of the present application. Thus, Smith fails to disclose, teach, or suggest each and every feature of independent claims 1 and 22 of the present application.

In the Advisory Action dated November 26, 2008, the Examiner contends that the drug delivery device of Smith is hand-operable even when it is in its protective casing. The Examiner admits that switch **22** that permits press-and-breath mode is converted into a breath actuated mode when the device is initially closed by flange **25** on the movable cover **38** used to cock the breath actuated inhaler. However, the Examiner contends that user is not precluded from opening the device by moving the cover **38** and attached flange **25** downward and then reactivating the switch **22** for the press-and-breath mode.

Applicants respectfully submit that even if the device in Smith operated in the manner as suggested by the Examiner, i.e., the switch **22** being activated after the loading of the container to fire by opening the cover **38**, it would still not anticipate claims 1 and 22 or the claims that depend therefrom. In particular, the device in Smith

cannot be hand-operated by triggering the switch **22** to deliver a drug composition as the patient inhales through an outlet of the device.

The purpose of the device in Smith is to provide an inhalation device. In particular, the switch **22** is to provide a press and breath operational mode as opposed to the device's other breath-actuated mode. In both operational modes, the intended purpose of the device in Smith is to deliver a medicament for inhalation by the patient at the time of the inhalation. When the container **6** is in the protective casing **34** in Smith, the only way to gain access to the switch **22** that has been reset to breath-actuated mode is to open the cover **38**. Whenever the movable cover **38** is opened in the device in Smith, the spring **48** above the container **6** automatically loads the container to cause compression (i.e., firing) of its valve once the catch **16** is deflected away from its connection with the vane **14** and the breath actuation mechanism is thus moved to its unblocking position. The valve and container cannot be reset until the cover **38** is closed. Thus, if the switch **22** were activated after opening of the cover **38**, as postulated by the Examiner, the container and valve would also be activated by consequential release of the compression in the spring **48,** and the valve and container would not be able to reset until the cover **38** is closed.

It is notable that the placement of the switch **22** in Smith is in very close proximity to the mouthpiece **4** of the device. This placement of the switch **22** prevents access to the switch **22** for actuation of the switch **22** when the mouthpiece **4** of the device is placed in the patient's mouth due to the immediate closeness of the switch **22** to the patient's face. Thus, since the switch **22** cannot be activated without automatically firing

the container **6,** and the container **6** cannot be reset without the switch **22** automatically being reset, the switch **22** could only be used once to fire the container on each opening of the cover **38**. Since the activation of the switch **22** automatically fires the container **6** which is cocked upon opening the cover **38,** and the activation of the switch **22** prevents effective inhalation through the mouthpiece **4** of the device in Smith, applicants respectfully submit that the device in Smith cannot be configured to be hand-operable to deliver a drug composition as the patient inhales through the mouthpiece **4** (outlet) when disposed in the protective casing.

Applicant also reiterates that it is essential for successful operation of the Smith device that the patient inhale through the mouthpiece **4** in coordination with release of content from the container **6,** because the inhalation moves the vane **14** to its position in which it does not impede flow of the container content out of the mouthpiece **4**.

For the reasons outlined above, applicants respectfully submit that Smith fails to anticipate claims 1 and 22 of the present application. Claims 3, 4, 6, 9-10, 13-21, 36, 37, 40 and 41 depend from claim 1. Claims 24-28 and 31-33 depend from claim 22. As such, applicants respectfully submit that the rejections of claims 1, 3, 4, 6, 9-10, 13-22, 24-28, 31-33, 36, 37, 40 and 41 under 35 U.S.C. §102(b) should be withdrawn and the claims allowed at this time.

Claim Rejections – 35 U.S.C. § 103

Claims 21, 38, 39, and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith. Claims 11-12 and 28-29 are rejected under 35 U.S.C. §

103(a) as being unpatentable over Smith in view of International Patent Publication No. WO 98/56444 to Rand et al. (hereinafter, "Rand"). These rejections are respectfully traversed.

Claim 21 depend from claim 1. As described above, Smith does not disclose, teach, or suggest all the features of claim 1. For example, Smith does not disclose, teach or suggest a drug delivery device with a dispensing unit that is configured to be hand-operated both when fixedly secured to the casing unit and when the dispensing unit is independent from the casing unit. In Smith, when the breath-actuated inhaler is disposed within the protective casing, whether or not the aerosol canister protrudes from the protective casing, the actuating condition is still only applied through inhalation, not hand-operation, because the breath actuation mechanism is in its blocking position until the patient inhales at the mouthpiece. Thus, claim 21 is not rendered obvious by Smith.

Claims 11-12 depend from claim 1 and claims 28-29 depend from claim 22. As stated above, Smith does not disclose, teach, or suggest all the features of claims 1 and 22. Rand does not overcome the significant shortcomings of Smith. Rand discloses a dispenser with a dose indicator therein. Rand, as with Smith, does not disclose, teach, or suggest, for example, a drug delivery device with a dispensing unit that is configured to be hand-operated both when fixedly secured to the casing unit and when the dispensing unit is independent from the casing unit. Thus, claims 11-12 and 28-29 are not rendered obvious by Smith.

Claims 38 and 42 have been rewritten into independent format to include the features of claim 1 and the other claims from which they originally depended. Further, Claims 38 and 42 have been amended to include that the first part of the container is inaccessible to the patient's digit when the casing unit is in its closed state. Claim 39 depends from claim 38. As stated above, Smith does not disclose, teach or suggest a drug delivery device with a dispensing unit that is configured to be hand-operated both when fixedly secured to the casing unit and when the dispensing unit is independent from the casing unit.

Further, with respect to the embodiment cited by the Examiner, Smith does not disclose, teach or suggest that the aerosol canister is accessible to a patient's digit when the protective casing is opened, but inaccessible to the patient's digit when the protective casing is closed. In most of the embodiments of Smith, the aerosol canister is inaccessible to the patient's digits when the protective casing is opened or closed. In the embodiment cited by the Examiner as providing accessibility when the protective casing is opened, the aerosol canister, through its protrusion through the protective casing, would be accessible both in the closed and open states of the outer protective casing.

Smith discloses modifications to the breath-actuated inhaler in Figures 8-10. In Figures 8a and 8b, the cocking spring **86** is provided between the inside surface of the protective casing **34** and a flange **84** on a shroud **82** for the aerosol canister **6**. In Figures 9a and 9b, an alternative cocking mechanism is shown in which an upper portion **90** of the protective casing is rotated about the inhaler axis to compress the

cocking spring **48**. Figures 10a and 10b incorporate the features of Figures 8 and 9. (See Smith, column 5, line 63 – column 6, line 51.)

As cited by the Examiner, with reference to Figures 8a, 8b, 10a, and 10b, Smith discloses that the shroud **82** can be dispensed with and replaced by a circumferential flange extending around the aerosol canister (vial) **6** against which the cocking spring **86** will act. (See Smith, column 6, lines 52-63.) When read in conjunction with column 3, lines 24-27 of Smith, the canister **6** may extend through the protective casing in this embodiment.

Therefore, with a circumferential flange around the aerosol canister instead of a shroud, it is clear that the aerosol canister would be accessible by a patient's digits both when the protective casing is opened and when the protective casing is closed. Thus, with respect to the embodiment cited by the Examiner, Smith does not disclose, teach, or suggest that that the aerosol canister is accessible to a patient's digit when the protective casing is opened, but inaccessible to the patient's digit when the protective casing is closed. Therefore, for the above reasons, claims 38, 39 and 42 are not rendered obvious by Smith.

Further, the arrangement of Smith shown in Figure 5 also does not disclose, teach, or suggest that the aerosol canister **6** is accessible to a patient's digit when the protective casing is opened, but inaccessible to the patient's digit when the protective casing is closed. The canister **6** in Figure 5 is clearly not accessible to the digit of a patient when the "casing unit" is in the open state. The protective casing unit **34**

prevents any access to the container **6** when the casing unit **34** is in both a closed state and an open state.

For the reasons set forth above, claims 11, 12, 21, 28, 29, 38, 39, and 42 are not rendered obvious by the cited references. Accordingly, applicants respectfully submit that the rejections of claims 11, 12, 21, 28, 29, 38, 39, and 42 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

New Claim

New claim 43 has been added. New independent claim 43 recites a method for delivering to a patient a drug composition from a container which contains the drug composition. The container is adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto which is a movement of a first part of the container relative to a second part of the container. Claim 43 recites that the method includes the step of providing a drug delivery device.

The drug delivery device includes a dispensing unit adapted to receive the container. The dispensing unit has an actuating mechanism hand-operable to apply the actuating condition to the container, and an outlet through which the drug composition is dispensable from the device. The actuating mechanism is configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container. The drug delivery device also includes a casing unit for the dispensing unit. The casing unit is configured to be movable between a closed state in which the casing unit covers the

outlet, and an open state in which the casing unit uncovers the outlet. The dispensing and casing units have securing features for fixedly securing the units together. Additionally, the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state. The securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit. The dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit.

Claim 43 also recites the steps of opening the casing unit to an open state and placing the outlet of the dispensing unit into the mouth of the patient. Claim 43 further recites the step of hand-operating the actuating mechanism of the dispensing unit to apply the actuating condition to the container to deliver the drug composition as the patient inhales through the outlet.

As outlined above, the cited references do not disclose such a drug delivery device as described above, opening its casing unit, and hand-operating the drug delivery device when the outlet is within a patient's mouth. As stated above, the device in Smith when it is disposed in the protective casing is not configured to be hand-operable to deliver a drug composition as the patient inhales through an outlet of the device. Moreover, there is no teaching in Smith to operate the switch **22** in the manner asserted by the Examiner. As outlined above, this is because any such operation of the switch **22** is inconsistent with proper operation of the Smith device when the aerosol

container **6** is disposed in the outer protective casing **34**. Therefore, it is respectfully submitted that new claim 43 is patentable over the cited art and is in condition for allowance.

CONCLUSION

In light of the above remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. **50-0426**.

Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

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